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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,230	05/08/2001	John Hamilton	E1679-00007	4015

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M. LISA WILSON
DUANE MORRIS LLP
380 LEXINGTON AVENUE
NEW YORK, NY 10168-0002

EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,230	HAMILTON ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Upon consideration of Applicant's argument during interview on 08/1/05, the rejection under 102(e) as being anticipated by US Patent 5,837,480 as set forth in the Advisory Action, mailed on 06/16/05 is herby withdrawn.

Claims 29-34 are pending and under consideration in the instant application.

In view of the new grounds of rejection presented below, the present Office Action is made **NON-FINAL.**

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

3. Claims 29-33 are rejected under 35 U.S.C. 102(a) as being anticipated by US 2002/0141994A1.

US Patent '994, teaches a method for ameliorating the effects of inflammation in a subject, comprising administering antibody specific for M-CSF (see entire document, page 2, paragraphs 22-24, page 3, paragraph 26 and page 6, paragraph 86 in particular). US Patent '994 teaches that administering of said antibody inhibit the effect of M-SCF on monocytes/macrophages (see column 6, paragraph 93 in particular).

Claims 30 and 33 are included because the claimed functional limitation would be inherent properties of the referenced antibodies against GM-CSF, because the claimed method for ameliorating the effects of inflammation and the referenced method using the same antibodies against GM-CSF. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The reference teaching anticipates the claimed invention.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,837,460 in view of Janeway et al. (Immunobiology, Third Edition, 1999, pages 650-651).

US Patent '460 teaches a method for ameliorating the effects of inflammation in a mammal , comprising administering to said mammal a therapeutically effective amount of an M-CSF or GM-CSF antigen or antibody to M-CSF or GM-CSF antibody. (see entire document, Abstract and columns 5 and 9 in particular). In other words, US Patent ' 460 teaches a method for treating inflammation in a mammal using method of active immunization with M-CSF or GM-CSF antigen.

US Patent '460 does not explicitly teaches a method for ameliorating the effects of inflammation in a mammal comprising administering to said animal a therapeutically effective amount of antibody to M-CSF, i.e passive immunization.

Janeway et al. teach that it is well known that treating diseases can be done by either passive immunization i.e. by administering to a patient an antiserum or purified antibodies specific for an antigen or by active immunization, i.e. by administering to a patient an antigen that will result in production of antigen-specific antibodies. Janeway et al. teach that passive immunization provides protection against many pathogens and should be used when immediate protection is required. (see pages 650-651 in particular).

It is noted that the reference method uses a method of active immunization (administering M-SCF or GM-SCF antigen to the patient) while the claimed method uses the method of passive

immunization (administering antibody to a M-CSF to the patient) to achieve the same results. It is clear that both the prior art and applicant administer the similar treatment, i.e. active and passive immunization against M-CSF to the same patient to achieve the same results, i.e. to treat inflammation. Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to apply teaching of Janeway et al., to those of US Patent '460 and substitute active immunization with M-CSF antigen with passive immunization with antibody M-CSF.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because both method of active and passive immunization were well known to one skilled in the art at the time the invention was made and passive immunization should be used when immediate protection is required as taught by Janeway et al. Thus passive immunization can be used instead of active immunization in the method of treating rheumatoid arthritis taught by US Patent '460.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6 Claims 29, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0141994A1 in view of US Patent 5444153 or US Patent 5662609.

The teachings of US 2002/0141994A1 has been discussed, supra.

The claimed invention differs from the reference teaching in that the US 2002/0141994A1 does not teach a method for ameliorating the effects of inflammation in a subject comprising administering antibodies against M-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

US Patent '153 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA (see entire document, Abstract column 2 and column 5, lines 55-65, and column 6 in particular).

US Patent '609 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA or inhibitors of agents which inhibits the effects of inflammatory mediators (see entire document, column 4 and column 6 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '153 or US Patent '609 to those of US 2002/0141994A1 to obtain a claimed method for ameliorating the effects of inflammation in a

subject comprising administering antibodies against M-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators can be used in the a method of treating inflammatory diseases as taught by US Patent '153 or US Patent '609 and can be combined with a method of treating inflammatory diseases in patients taught by WO 00/09561 or JP 2000198799 or US Patent 5,837,460. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Claims 29, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,837,460 in view of Janeway et al,. as applied to claims 29-33 above, and further in view of US Patent 5444153 or US Patent 5662609.

The teachings of US Patent 5,837,460 and Janeway et al,. have been discussed, supra.

The claimed invention differs from the reference teaching in that the US Patent 5,837,460 and Janeway et al., do not teach a method for ameliorating the effects of inflammation in a subject comprising administering antibodies against M-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

US Patent '153 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA (see entire document, Abstract column 2 and column 5, lines 55-65, and column 6 in particular).

US Patent '609 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA or inhibitors of agents which inhibits the effects of inflammatory mediators (see entire document, column 4 and column 6 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '153 or US Patent '609 to those of US Patent 5,837,460 and Janeway et al., to obtain a claimed method for ameliorating the effects of inflammation in a subject comprising administering antibodies against M-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators can be used in the a method of treating inflammatory diseases as taught by US Patent '153 or US Patent '609 and can be combined with a method of treating inflammatory diseases in patients taught by WO 00/09561 or JP 2000198799 or US Patent 5,837,460. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
August 8, 2005

Christina Chan
CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600